

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Andrew McMichael, Adrian V.S. Hill, Sarah C. Gilbert, Jörg Schneider,
Magdalena Plebanski, Tomas Hanke, Geoffrey L. Smith and Tom Blanchard

Application No.: 10/686,943 Group Art Unit: 1648

Filed: October 16, 2003 Examiner: Louise Humphrey, Ph.D.

Confirmation No.: 4585

Title: METHODS AND REAGENTS FOR VACCINATION WHICH GENERATE A
CD8 T CELL IMMUNE RESPONSE



CERTIFICATE OF MAILING OR TRANSMISSION	
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THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
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Sir:

This Third Supplemental Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)

☐ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☒ under 37 CFR 1.97(c) together with either:

☐ a Statement under 37 CFR 1.97(e), as checked below, or

☒ a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:

☐ a Statement under 37 CFR 1.97(e), as checked below, and

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application file.

(Filed after payment of issue fee)

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Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
 - ☒ Copies of the cited references, B1-B10, C1-C62, are enclosed.
 - ☐ Copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
 - ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed. The earlier application contains copies of the cited references.
 - ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
 - ☒ The "concise explanation" requirement (non-English references) for references B8, B9, C31, C37 and C59 under 37 CFR 1.98(a)(3) is satisfied by:
 - ☐ the explanation provided on the attached sheet.
 - ☐ the explanation provided in the Specification.
 - ☐ submission of the enclosed International Search Report.
 - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
 - ☒ the enclosed English language abstracts.

- ☒ Applicants request that the following non-published applications be considered:
(Affix a label or apply the stamp "Non-Published IDS Reference - Do Not Scan" to the front of each unpublished pending appl'n.)

Examiner's
Initials

- ____ U.S. Patent Application No. 60/148,981, by Ling Chen, John Shiver, Andrew Bett, Danilo Riguera Casimiro, Michael J. Caulfield, Michael A. Chastain and Emilio A. Emini, filed August 13, 1999.
- ____ U.S. Patent Application No. 60/150,728, by Michael P. Neeper, William L. McClements, Kathrin U. Jansen, Loren D. Schultz, Ling Chen and Xin-Min Wang, filed August 25, 1999.
- ____ U.S. Patent Application No. 60/680,838, by Andrew McMichael, Adrian V. S. Hill, Sarah C. Gilbert, Jörg Schneider, Magdalena Plebanski, Tom Hanke, Geoffrey L. Smith, Tom Blanchard and Martin Cripps, filed May 13, 2005, Docket No.: 3022.1002-000.
- ____ U.S. Patent Application No. 60/683,877, by Adrian V. S. Hill, Sarah C. Gilbert, Jörg Schneider and Geoffrey L. Smith, filed May 23, 2005, Docket No.: 3022.1003-000.
- ____ U.S. Patent Application No. 60/782,710, by Jörg Schneider, Jamie Chorlton, Gill Pearce, Nicola Jones and Dean Brown, filed March 15, 2006, Docket No.: 3022.1003-001.
- ____ U.S. Patent Application No. 10/088,677, by Jörg Schneider, Sarah C. Gilbert, Carolyn M. Hannan and Adrian V.S. Hill, 371 (c) date: May 31, 2002, Docket No.: 3022.1004-000.

Examiner

Date

- ☒ A copy of each above-cited application, including the current claims for U.S. Patent Application No. 10/088,677, is enclosed.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

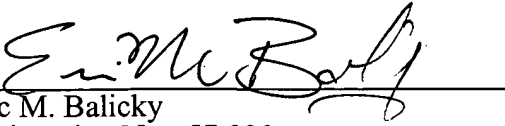
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- ☐ Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.

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Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

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Dated:

November 6, 2006

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DATE CONSIDERED

PTO-1449 REPRODUCED THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION November 6, 2006 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 2907.1000-003		APPLICATION NO. 10/686,943	
	FIRST NAMED INVENTOR Andrew McMichael		FILING DATE October 16, 2003	
	EXAMINER Louise Humphrey, Ph.D.	CONFIRMATION NO. 4585	GROUP 1648	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

C1	Afonso, C.L., <i>et al.</i> , "The Genome of Fowlpox Virus," <i>J. Virol.</i> 74(8):3815-3831 (2000).
C2	Anderson, <i>et al.</i> , "Enhanced CD8 T Cell Response and Protective Efficacy Against Malaria Using Recombinant Fowlpox Virus In Heterologous Prime/Boost Immunisation Regimes," Abstract, <i>Immunology</i> 101(Supplement 1):32 (2000).
C3	Berkner, K.L., "Development of Adenovirus Vectors for the Expression of Heterologous Genes," <i>BioTechniques</i> 6(7): 616-629 (1988).
C4	Boulanger, D., <i>et al.</i> , "Morphogenesis and Release of Fowlpox Virus," <i>J. Gen. Virol.</i> 81:675-687 (2000).
C5	Boulanger, D., <i>et al.</i> , "The 131-Amino-Acid Repeat Region of the Essential 39-Kilodalton Core Protein of Fowlpox Virus FP9, Equivilant to Vaccinia Virus A4L Protein, Is Nonessential and Highly Immunogenic," <i>J. Virol</i> 72(1):170-179 (1998).
C6	Boursnell, M.E.G., <i>et al.</i> , "A Fowlpox Virus Vaccine Vector with Insertion Sites in the Terminal Repeats: Demonstration of its Efficacy Using the Fusion Gene of Newcastle Disease Virus," <i>Vet. Microbiol.</i> 23:305-316 (1990).
C7	Boursnell, M.E.G., <i>et al.</i> , "Insertion of the Fusion Gene from Newcastle Disease Virus into a Non-essential Region in the Terminal Repeats of Fowlpox Virus and Demonstration of Protective Immunity Induced by the Recombinant," <i>J. Gen. Virology</i> 71:621-628 (1990).
C8	Boyle, D.B. and Heine, H.G., "Recombinant Fowlpox Virus Vaccines for Poultry," <i>Immunol. Cell Biol.</i> 71:391-397 (1993).
C9	Boyle, D.B., <i>et al.</i> , "Comparison of Field and Vaccine Strains of Australian Fowlpox Viruses," <i>Arch. Virol.</i> 142:737-748 (1997).
C10	Brooks, J.V., <i>et al.</i> , "Boosting Vaccine for Tuberculosis," <i>Infect. Immun.</i> 69(4): 2714-2717 (2001).
C11	Buge, S.L., <i>et al.</i> , "Factors Associated with Slow Disease Progression in Macaques Immunized with an Adenovirus-Simian Immunodeficiency Virus (SIV) Envelope Priming-gp120 Boosting Regimen and Challenged Vaginally with SIVmac251," <i>J. Virol.</i> 73(9):7430-7440 (1999).
C12	Campbell, J.I.A., <i>et al.</i> , "Tandem Repeated Sequences Within the Terminal Region of the Fowlpox Virus Genome," <i>J. Gen. Virol.</i> 70:145-154 (1989).

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	C13	Carter, B.J., <i>et al.</i> , "Gene Therapy as Drug Development," <i>Mol. Therapy</i> 1:(3)211-212 (2000).
	C14	Carvalho, L.J.M., <i>et al.</i> , "Malaria Vaccine: Candidate Antigens, Mechanisms, Constraints and Prospects," <i>Scand. J. Immunol.</i> 56:327-343 (2002).
	C15	Conry, R.M., <i>et al.</i> , "Safety and Immunogenicity of a DNA Vaccine Encoding Carcinoembryonic Antigen and Hepatitis B Surface Antigen in Colorectal Carcinoma Patients," <i>Clin. Cancer Res.</i> 8:2782-2787 (2002).
	C16	Coupar, B.E.H., <i>et al.</i> , "Restriction Endonuclease Mapping of the Fowlpox Virus Genome," <i>Virology</i> 179:159-167 (1990).
	C17	Dale, C. J., <i>et al.</i> , "Induction of HIV-1-Specific T-Helper Responses and Type 1 Cytokine Secretion Following Therapeutic Vaccination of Macaques with a Recombinant Fowlpoxvirus Co-expressing Interferon-Gamma," <i>J. Med. Primatol.</i> 29:240-247 (2000).
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	C19	Denis, O., <i>et al.</i> , "Vaccination with Plasmid DNA Encoding Mycobacterial Antigen 85A Stimulates a CD4+ and CD8+ T-Cell Epitopic Repertoire Broader than that Stimulated by <i>Mycobacterium tuberculosis</i> H37Rv Infection," <i>Infect. Immun.</i> 66(4):1527-1533 (1998)
	C20	E-mail dated January 5, 2006 from American Society for Microbiology re: Date of Disclosure of Buge's Document.
	C21	Grosenbach, D. W., <i>et al.</i> , "Synergy of Vaccine Strategies to Amplify Antigen-specific Immune Responses and Antitumor Effects," <i>Cancer Res</i> 61:4497-4505 (2001).
	C22	Hertig, C., <i>et al.</i> , "Field and Vaccine Strains of Fowlpox Virus Carry Integrated Sequences from the Avian Retrovirus, Reticuloendotheliosis Virus," <i>Virology</i> 35:367-376 (1997).
	C23	Holder, A., <i>et al.</i> , "Falciparum Malaria MSP1 Workshop: Progress toward MSP1 Vaccine Development and Testing," <i>Malaria Vaccine Initiative at PATH</i> : 1-30 (2000).

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C24	Johnson, R.P., <i>et al.</i> , "Induction of a Major Histocompatibility Complex Class I-Restricted Cytotoxic T-Lymphocyte Response to a Highly Conserved Region of Human Immunodeficiency Virus Type 1 (HIV-1) gp120 in Seronegative Humans Immunized with a Candidate HIV-1 Vaccine," <i>J. Virol.</i> 68(5):3145-3153 (1994).
C25	Kazanji, M., <i>et al.</i> "Expression and Immunogenicity in Rats of Recombinant Adenovirus 5 DNA Plasmids and Vaccinia Virus Containing the HTLV-I <i>inv</i> Gene," <i>Int. J. Cancer</i> 71:300-307 (1997).
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C27	Kent, S.J., <i>et al.</i> , "Enhanced T-Cell Immunogenicity and Protective Efficacy of a Human Immunodeficiency Virus Type 1 Vaccine Regimen Consisting of Consecutive Priming with DNA and Boosting with Recombinant Fowlpox Virus," <i>J. Virol.</i> 72(12):10180-10188 (1998).
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C29	Laidlaw, S.M. and Skinner, M.A., "Comparison of the Genome Sequence of FP9, an Attenuated, Tissue Culture-adapted European Strain of <i>Fowlpox virus</i> , with Those of Virulent American and European Viruses," <i>J. Gen. Virol.</i> 85:305-322 (2004).
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C33	Moss, B., "Genetically Engineered Poxviruses for Recombinant Gene Expression, Vaccination, and Safety," <i>Proc. Natl. Acad. Sci. USA</i> 93:11341-11348 (1996).
C34	Natuk, R.J., <i>et al.</i> , "Immunogenicity of Recombinant Human Adenovirus-Human Immunodeficiency Virus Vaccines in Chimpanzees," <i>Aids Res. Hum. Retroviruses</i> (9):395-404 (1993).

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C35	NCBI Accession No. AF198100, "Fowlpox virus, complete genome," [online], March 2000. [retrieved on 2006-09-14] Retrieved from the Internet <URL:http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?db=nucleotide&val=7271507>.
C36	Niewiesk, S., <i>et al.</i> , "Measles Virus-Induced Immune Suppression in the Cotton Rat (<i>Sigmodon hispidus</i>) Model Depends on Viral Glycoproteins," <i>J. Virol.</i> 71(10):7214-7219 (1997).
C37	Notice of Opposition to a European Patent. Patent No.: EP 1 214 416. Opponent: Transgene S.A. (English translation attached.)
C38	Notice of Opposition to a European Patent. Patent No.: EP 1 214 416 B1. Opponent: Merck & Co., Inc.
C39	Notice of Opposition to a European Patent. Patent No.: EP 1 214 416 B1. Opponent: Crucell Holland B.V.
C40	Paoletti, E., "Applications of Pox Virus Vectors to Vaccination: An Update," <i>Proc. Natl. Acad. Sci. USA</i> 93:11349-11353 (1996).
C41	Pollitt, E., <i>et al.</i> , "Nucleotide Sequence of the 4.3 kbp BamHI-N Fragment of Fowlpox Virus FP9," <i>Virus Genes</i> 17(1):5-9 (1998).
C42	Qingzhong, Y., <i>et al.</i> , "Protection Against Turkey Rhinotracheitis Pneumovirus (TRTV) Induced by a Fowlpox Virus Recombinant Expressing the TRTV Fusion Glycoprotein (F)," <i>Vaccine</i> 12(6):569-573 (1994).
C43	Ramarathinam, L., <i>et al.</i> , "Multiple Lineages of Tumors Express a Common Tumor Antigen, P1A, but they are not Cross-Protected," <i>J. Immunol.</i> 155: 5323-5329 (1995).
C44	Robert-Guroff, M., <i>et al.</i> , "Vaccine Protection Against a Heterologous, Non-Syncytium-Inducing, Primary Human Immunodeficiency Virus," <i>J. Virol.</i> 72(12):10275-10280 (1998).
C45	Robinson, H.L., <i>et al.</i> , "Neutralizing Antibody-independent Containment of Immunodeficiency Virus Challenges by DNA Priming and Recombinant Pox Virus Booster Immunizations," <i>Nature Med.</i> 5(5):526-534 (1999).
C46	Rodrigues, E.G., <i>et al.</i> , "Efficient Induction of Protective Anti-Malaria Immunity By Recombinant Adenovirus," <i>Vaccine</i> 16(19):1812-1817, (1998).

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

C47	Rothel, J.S., <i>et al.</i> , "Sequential Nucleic Acid and Recombinant Adenovirus Vaccination Induces Host-protective Immune Responses Against <i>Taenia ovis</i> infection in Sheep," <i>Parasite Immunology</i> 19:221-227 (1997).
C48	Shah, K.V. and Howley, P.M., "Papillomaviruses." In <i>Fields Virology</i> , B.N. Fields, <i>et al.</i> , eds. (PA: Lippincott-Raven Publishers) pp. 2077-2109 (1996).
C49	Shaw, I. and Davison, T.F., "Protection From IBDV-Induced Bursal Damage By A Recombinant Fowlpox Vaccine, fplBD1, Is Dependent ON the Titre of Challenge Virus and Chicken Genotype," <i>Vaccine</i> 18:3230-3241 (2000).
C50	Skinner, M.A., <i>et al.</i> , "Fowlpox Virus as a Recombinant Vaccine Vector for use in Mammals and Poultry," <i>Expert Rev. Vaccines</i> 4(1):63-76 (2005).
C51	Somogyi, P., <i>et al.</i> , "Fowlpox Virus Host Range Restriction: Gene Expression, DNA Replication, and Morphogenesis in Nonpermissive Mammalian Cells," <i>Virology</i> 197:439-444 (1993).
C52	Sutter, G. and Moss, B., "Nonreplicating Vaccinia Vector Efficiently Expresses Recombinant Genes," <i>Proc. Natl. Acad. Sci. USA</i> , 89:10847-10851 (1992).
C53	Tanghe, A., <i>et al.</i> , "Improved Immunogenicity and Protective Efficacy of a Tuberculosis DNA Vaccine Encoding Ag85 by Protein Boosting," <i>Infect. Immun.</i> 69(5):3041-3047 (2001).
C54	Taylor, J. and Paoletti, E., "Fowlpox Virus As A Vector in Non-Avian Species," <i>Vaccine</i> 6:466-468 (1988).
C55	Taylor, J., <i>et al.</i> , "Protective Immunity Against Avian Influenza Induced by a Fowlpox Virus Recombinant," <i>Vaccine</i> 6:504-508 (1988).
C56	Taylor, J., <i>et al.</i> , "Recombinant Fowlpox Virus Inducing Protective Immunity in Non-Avian Species," <i>Vaccine</i> 6(6):497-503 (1988).
C57	Thomson, S.A., <i>et al.</i> , "Delivery of Multiple CD8 Cytotoxic T Cell Epitopes by DNA Vaccination," <i>J. Immunol.</i> 160:1717-1723 (1998).

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